REMARKS

The Office Action and the Advisory Actions dated February 4 and March 11, 2004 have been carefully reviewed. No claim is allowed. Claims 41, 46-48, and 53-61 presently appear in this application, with claims 56 and 58 newly added to replace unentered claims 49-52, and define patentable subject matter warranting their allowance. Reconsideration and allowance are hereby respectfully solicited.

In a brief telephone discussion with the examiner on February 11, 2004, to clarify the new issues noted in the Advisory Action of February 4, 2004, the examiner indicated that the new issues relate to duplicate claims and the cancellation of duplicate claims, as amended in the amendment dated December 17, 2003, would appear to resolve any outstanding issues and place the application in condition for allowance. Claims 43-45 are now cancelled, thereby obviating the new issue of duplicate claims as noted on the Advisory Action of February 4, 2004.

Claims 41-48 have been rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. This rejection is respectfully traversed.

Claim 41 is amended to replace the recitation of hybridization with the recitation of "no more than ten amino acid changes from the amino acid sequence of SEQ ID NO:2, each of said changes being alternative conservative substitutions within one of the following five groups of amino acid residues", as supported in the specification at page 26, lines 14-17 and page 28, lines 7-20. Furthermore, new claims 56, 58, and 60 are directed to "no more than five", "no more than three" and a "single" amino acid change(s), respectively, as supported at page 26, lines 9-17, of the instant specification. It is believed that the amendments to the claims obviate the written description rejection.

The situation here is similar to Example 14: Product by Function of the USPTO "Revised Interim Written Description Guidelines Training Materials", where the claim in the example reads as follows:

> A protein having SEQ ID NO:3 and variants thereof that are at least 95% identical to SEQ ID NO:3 and catalyze the reaction of A→B.

The analysis indicates that the procedures for making variants of SEQ ID NO:3 are conventional in the art and an assay is described which will identify other proteins having the claimed catalytic activity. The analysis further teaches that:

> The single species disclosed is representative of the genus because all members have at least 95% structural identity with the reference compound and because of the presence of an assay which applicant provided for identifying all of the at least 95% identical variants of SEQ ID NO:3 which are capable of the specified catalytic activity. One of skill in the art would conclude that applicant was in possession of the necessary common attributes possessed by the members of the genus.

The mouse GILR protein of SEQ ID NO:2 is 137 residues in length. A variant as claimed in claim 41 can have no more than ten amino acid changes from the sequence of SEQ ID NO:2, which is equivalent to at least 127/137 x 100%=92.7% sequence identity. New claims 56 and 58 are directed to variants with no more than five and no more than three amino acid changes, which correspond to at least 96.3% and 97.8% sequence identity, respectively. While 96.3% and 97.2% sequence identities are clearly at higher levels of sequence identity than the 95% sequence identity shown in Example 14 discussed above, the 92.7% sequence identity is also very close to the 95% level and the teaching in Example 14 should be considered to be quite relevant to the recitation of "no more than ten amino acid changes from the sequence of SEQ ID NO:2" recited in claim 41.

The procedures for making variants are indeed conventional in the art and the specification discloses from page

56, line 19 to page 57, line 10, and from page 1, line 3 to page 64, line 11, assays to identify proteins and variants having the claimed apoptosis inhibiting and lymphocyte stimulating activities recited in the claims. Accordingly, the claims as amended comply with the written description requirements of 35 U.S.C. §112, first paragraph.

Reconsideration and withdrawal of the rejection are therefore respectfully requested.

In the Advisory Action dated March 11, 2004, the examiner stated that this amendment raises new issues under 35 U.S.C. §112, 1st paragraph, since the instant claims read on an exponential number of proteins having the cited structure, however apart from trial and error experimentation de novo experimentation, there is no particular guidance to instruct the skilled artisan how to pick and choose which of these proteins would function to inhibit apoptosis and stimulate lymphocyte activity. Although Figure 15 shows an alignment between the mouse and human GILR proteins, wherein the two proteins differ at 11 positions, the examiner notes that the instant claims are not limited to wherein said changes occur at the 11 differential positions between the mouse and the human GILR proteins as indicated by Figure 15.

New claims 55, 57, 59, and 61 now specifically recite the 11 amino acid residue positions at which mouse and human GILR differ, as shown in Fig. 15, as the locations where changes are to be made. Furthermore, the presence of an amino acid sequence alignment as shown in Fig. 15, along with the disclosed five groups of alternative substitutions, the comparison of the leucine zipper motif in Fig. 4, and the complete sequence alignment with TSC-22 (a protein in the leucine zipper family) provide a person of skill in the art, where the level of skill in quite high, with sufficient guidance so that this same person would be able to select amino acid changes which would have a high expectation of retaining the activity of the GILR protein of SEQ ID NO:2. Accordingly, the present claims are fully enabled by the specification and drawings.

In view of the above, the claims comply with 35 U.S.C. §112 and define patentable subject matter warranting their allowance. Favorable consideration and early allowance are earnestly urged.

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allowance. Favorable consideration and early allowance are earnestly urged.

Respectfully submitted,

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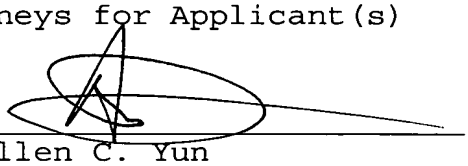
By 
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